PATENT
ATTORNEY DOCKET NO. P-8263

UTILITY APPLICATION FOR UNITED STATES LETTERS PATENT

FOR

DUAL-CHAMBER PACEMAKER SYSTEM FOR SIMULTANEOUS BI-CHAMBER PACING AND SENSING

BY

MALCOLM BEGEMANN
BIESDELSELAAN 12 A
6881 CG VELP
THE NETHERLANDS

and

GEESKE VAN OORT
PASTOOR HORDIJKSTRAAT 54
5243 VX ROSMALEN
THE NETHERLANDS

ATTORNEY OF RECORD: Thomas F. Woods, Reg. No. 36,726
medtronic, inc.

DUAL-CHAMBER PACEMAKER SYSTEM FOR SIMULTANEOUS BI-CHAMBER PACING AND SENSING

FIELD OF THE INVENTION

The present invention relates to the field of implantable medical devices, and, more particularly, to dual-chamber cardiac pacing systems that are capable of switching electrode configurations when two unipolar leads are disposed in opposing heart chambers (i.e., left and right atria or left and right ventricles).

BACKGROUND OF THE INVENTION

Tachyarrhythmias are episodes of high-rate cardiac depolarizations. Tachyarrhythmias may occur in one chamber of the heart or may be propagated from one chamber to another. Some tachyarrhythmias are sufficiently high in rate to compromise cardiac output from the chamber(s) affected, leading to loss consciousness or death, in the case of ventricular fibrillation or weakness and dizziness in the case of atrial fibrillation. Atrial fibrillation is often debilitating, due to the loss of atrial cardiac output, and may sometimes lead to ventricular fibrillation.

Generally, fibrillation may be terminated by administering high energy level cardioversion/defibrillation shocks or pulses until the fibrillation is terminated. For example, in the context of implantable anti-arrhythmia devices, these pulses may be applied by means of large surface area electrodes on or in the chamber to be defibrillated. However, the high energy level pulses are often sufficient to cause pain to the patient. Thus, it would be desirable to prevent or decrease the occurrence of atrial fibrillation without the delivery of high energy level pulses.

Some exploration has, therefore, been made in the use of pacing level pulses, which stimulate the cardiac tissue at much lower levels than defibrillation pulses, to terminate atrial fibrillation.

Implantable pulse generators (IPGs) that deliver pacing level pulses are well known in the art. These IPGs may deliver pulses to one or more chambers of the heart. Some of these devices provide pacing stimuli to the heart at a predetermined rate. The stimuli may be applied at a fixed rate, on demand, at a rate synchronized to atrial activity or at a rate synchronized to ventricular activity. This type of pacing function may also be used in other devices such as, for example, implantable cardioverter defibrillators (ICDs) or in external pacemakers. Most IPGs include sense amplifier circuitry for detecting intrinsic cardiac electrical activity. Some IPGs also include sensors or sensing electrodes to determine reliably the heart rate (or pacing rate) in a heart under different conditions. Some IPGs are dual-chamber, having both atrial and ventricular leads. These IPGs have a unipolar lead in the ventricle and a unipolar lead in the atrium.

To deliver pacing pulses of sufficient magnitude to have the desired effect, it may be desirable to stimulate or sense more than one chamber of the heart simultaneously. This may be desirable, for example, because the simultaneous stimulation in opposing chambers results in stimulation pulses of higher amplitude or duration. This may also be desirable because stimulation across opposing chambers of the heart stimulates a desired location of tissue that is more difficult to stimulate across only one chamber of the heart. In standard IPGs, a minimum atrio-ventricular delay makes such simultaneous stimulation difficult or impossible. That is, there is a minimum delay between the time a first chamber, for example the left atria, is stimulated/sensed and the time the second chamber, for example the right atria, is stimulated/sensed.

It would also be desirable to provide stimulation to opposing chambers of the heart using standard programming settings and existing fixed connections in an IPG without the addition of further splitters and adapters.

It would also be desirable to provide switchable configurations of electrodes disposed in opposing atria or ventricles of the heart.

Thus, a need exists in the medical arts for simultaneous stimulation and/or sensing of opposing chambers of a heart.

Several methods have been proposed in the prior art for improving an implantable device's ability to administer pacing pulses simultaneously to more than one chamber of a heart.

For example, U.S. Patent No. 5,514,161 to Limousin, entitled "Methods and Apparatus for Controlling Atrial Stimulation in a Double Atrial Triple Chamber Cardiac Pacemaker", hereby incorporated by reference in its entirety, discloses a double atrial triple chamber pacemaker, which provides simultaneous stimulation to both atria through the provision of a Y connector.

U.S. Patent No. 5,757,970 to Pouvreau, entitled "System, Adaptor and Method to Provide Medical Electrical Stimulation" discloses an adaptor that permits a single channel of stimulation to be split and provided to two areas of the heart by adjusting the amplitude of the stimulation pulses.

The article "Permanent Multisite Cardiac Pacing" by Barold, et al. in the journal *PACE* discloses the use of a Y connector to split a standard bipolar output into anode and cathode electrodes.

The article "Hemodynamic Benefits of Permanent Atrial Resynchronization Patients with Advanced Inter Atrial Blocks, paced DDD Mode" by Daubert et al. in the journal *PACE* discloses the use of a bifurcated electrode to pace between the right atrium and the coronary sinus in order to pace both atria simultaneously.

As discussed above, the most pertinent prior art patents are shown in the following table:

Table 1. Prior Art Publications

Patent No.	Date	Inventor(s)
US 5,514,161	5-7-1996	Limousin
US 5,757,970	8-25-1998	Pouvreau

Barold et al. (November 1997) "System, Adaptor and Method to Provide Medical Electrical Stimulation" *PACE*, Vol. 20, pages 2725-2729.

Daubert et al. (April 1997) "Hemodynamic Benefits of Permanent Atrial Resychronization Patients with Advanced Inter Atrial Blocks, paced DDD Mode" *PACE*, Vol. 14, Part II, page 640, #130.

All the publications listed in Table 1 are hereby incorporated by reference herein in their respective entireties. As those of ordinary skill in the art will appreciate readily upon reading the Summary of the Invention, the Detailed Description of the Preferred Embodiments and the Claims set forth below, many of the devices and methods disclosed in the patents of Table **1** may be modified advantageously by using the teachings of the present invention.

SUMMARY OF THE INVENTION

The present invention is therefore directed to providing a method and system for simultaneously stimulating and/or sensing opposing chambers of the heart. The system of the present invention overcomes at least some of the problems, disadvantages and limitations of the prior art described above, and provides a more efficient and accurate means of stimulating opposing chambers of a heart.

The present invention has certain objects. That is, various embodiments of the present invention provide solutions to one or more problems existing in the

prior art respecting the pacing of cardiac tissue. Those problems include, without limitation: (a) difficulty in simultaneous stimulation of opposing chambers of the heart; (b) need to add splitters, adapters and additional circuitry to an existing IPG in order to accomplish simultaneous stimulation; (c) difficulty in determining appropriate sensing configurations using one or more leads; (d) difficulty in optimizing contractions induced in an opposing chamber of the heart; (e) difficulty in varying cathode and anode functions of electrodes disposed in opposing chambers, (f) difficulty in testing and determining which chamber of the heart provides the lowest pacing threshold; (g) difficulty in configuring electrodes already disposed in opposing chambers of the heart to take advantage of the lowest pacing threshold; (h) need to change circuitry or software/firmware in order to switch electrode configurations.

In comparison to known pacing techniques, various embodiments of the present invention provide one or more of the following advantages: (a) ability to provide simultaneous stimulation to opposing chambers of a heart; (b) ability to provide bi-atrial or bi-ventricular stimulation without an atrio-ventricular delay; (c) ability to reversibly select an anode electrode and a cathode electrode for simultaneous stimulation without removing either electrode from its existing connection; (d) ability to switch and/or select electrode configurations of electrodes already disposed in opposing chambers of the heart; (e) ability to switch and/or select polarity of a given electrode already disposed in a chamber of the heart; (f) ability to optimize hemodynamics of induced contractions in an opposing chamber of the heart; (g) ability to test and determine the chamber having the lowest pacing threshold and configure the electrodes to take advantage of the lowest pacing threshold without using specialized lead adapters; and (h) ability to test and determine the chamber having the lowest pacing threshold and configure the electrodes to take advantage of the lowest

pacing threshold without removing the leads from the connector block and re-inserting them in different connector receptacles.

Some embodiments of the present invention include one or more of the following features: (a) an IPG capable of providing bi-atrial or bi-ventricular stimulation without an atrio-ventricular delay; (b) an IPG capable of reversibly switching anode and cathode electrodes for simultaneous stimulation without additional adapters or connectors; (c) an IPG capable of testing opposing chambers to determine which chamber has the lowest pacing threshold and of configuring the electrodes to take advantage of the lowest pacing threshold; (d) an IPG in which the polarity of various electrodes is selectable and/or switchable; (e) an IPG capable of providing staggered stimulation to optimize hemodynamics of induced contractions (f) methods of reversibly selecting an anode electrode and a cathode electrode for simultaneous stimulation without removing either electrode from its existing connection; (g) methods of switching and/or selecting electrode configurations of electrodes already disposed in opposing chambers of the heart; (h) methods of switching and/or selecting polarity of a given electrode disposed in a chamber of the heart; and (i) methods of optimizing hemodynamics of induced contractions in an opposing chamber of the heart.

BRIEF DESCRIPTION OF THE DRAWINGS

The above, and other objects, advantages and features of the present invention will be more readily understood from the following detailed description of the preferred embodiments thereof, when considered in conjunction with the drawings, in which like reference numerals indicate identical structures throughout the several views, and wherein:

FIG. 1 is a schematic view of one embodiment of an implantable medical device *in situ*, made in accordance with the present invention;

FIG. 2 is another schematic view of an embodiment of the implantable medical device of **FIG. 1**, made in accordance with the present invention;

FIG. 3 is a block diagram illustrating components of an embodiment of the implantable medical device of **FIG. 1**, made in accordance with the present invention;

FIG. 4 is a schematic view of another embodiment of an implantable medical device, made in accordance with the present invention;

FIG. 5 is a block diagram illustrating components of an embodiment of the implantable medical device of **FIG. 4**, made in accordance with the present invention;

FIG. 6 is a schematic view of one embodiment of an implantable medical device for comparison with the present invention;

FIG. 7 is a schematic view illustrating components of one embodiment of an implantable medical device, made in accordance with the present invention;

FIG. 8 is a schematic view illustrating one configuration of the components of the embodiment of the implantable medical device of **FIG. 7;**

FIG. 9 is a schematic view illustrating one configuration of the components of the embodiment of the implantable medical device of **FIG. 7;**

FIG. 10 is a schematic view illustrating one configuration of the components of the embodiment of the implantable medical device of **FIG. 7;**

FIG. 11 is a schematic view illustrating one configuration of the components of the embodiment of the implantable medical device of **FIG. 7;**

FIG. 12 is a flow diagram of one embodiment of a method for stimulating a heart in accordance with the present invention;

FIG. 13 is a flow diagram of another embodiment of a method for stimulating a heart in accordance with the present invention.

DETAILED DESCRIPTION OF THE
PRESENTLY PREFERRED EMBODIMENTS

It is to be understood that the terms "IPG" and "IMD", as employed in the specification and claims hereof, connote an implantable medical device capable of delivering electrical stimuli to cardiac tissue, and include within their scope pacemakers, PCDs, ICDs, etc.

FIG. 1 is a simplified schematic view of one embodiment of implantable medical device ("IMD") **10** of the present invention. The IMD **10** shown in **FIG. 1** is a pacemaker comprising at least one of pacing and sensing leads **16** and **18** attached to hermetically sealed enclosure **14** and implanted near human or mammalian heart **8**. Pacing and sensing leads **16** and **18** sense electrical signals attendant to the depolarization and re-polarization of the heart **8**, and further provide pacing pulses for causing depolarization of cardiac tissue in the vicinity of the distal ends thereof. Sensing leads **16, 18** may serve, for example, as sensors to sense an atrial response (such as an atrial sensed response or an atrial pulse signal) in accordance with the present invention. One or both of leads **16, 18** may also serve to sense a ventricular response in accordance with the present invention. Leads **16** and **18** may have unipolar or bipolar electrodes disposed thereon, as is well known in the art. Examples of IMD **10** include implantable cardiac pacemakers disclosed in U.S. Patent No. 5,158,078 to Bennett *et al.*, U.S. Patent No. 5,312,453 to Shelton *et al.* or U.S. Patent No. 5,144,949 to Olson, all of which are hereby incorporated by reference, each in their respective entireties.

FIG. 2 shows connector module **12** and hermetically sealed enclosure **14** of IMD **10** located in and near human or mammalian heart **8**. Atrial and ventricular pacing leads **16** and **18** extend from connector header module **12** to the right atrium and ventricle, respectively, of heart **8**. Atrial electrodes **20** and **21** disposed at the distal end of atrial pacing lead **16** may be located in the right atrium. Alternatively, in accordance with the present invention, at least one of atrial electrodes **20, 21** may be located in the left atrium. In one embodiment of the invention, one or both of atrial electrodes **20, 21** may serve as sensors to sense an atrial response (such as an atrial sensed response or an atrial pulse signal) in accordance with the present invention. Ventricular electrodes **28** and **29** at the distal end of ventricular pacing lead **18** are located in the right ventricle. Alternatively, in accordance with the present invention, at least one of the ventricular electrodes **28, 29** may be located in the left ventricle. One or both of ventricular electrodes **28, 29** may also serve to sense a ventricular response in accordance with the present invention.

FIG. 3 shows a block diagram illustrating the constituent components of IMD **10** in accordance with one embodiment of the present invention, where IMD **10** is a pacemaker having a microprocessor-based architecture. IMD **10** is shown as including activity sensor or accelerometer **11**, which may be an accelerometer bonded to a hybrid circuit located inside enclosure **14**. Activity sensor **11** typically (although not necessarily) provides a sensor output that varies as a function of a measured parameter relating to a patient's metabolic requirements. For the sake of convenience, IMD **10** in **FIG. 3** is shown with lead **18** only connected thereto; similar circuitry and connections not explicitly shown in **FIG. 3** apply to lead **16**.

IMD **10** in **FIG. 3** may be programmable by means of an external programming unit (not shown in the Figures). One such programmer is the commercially available Medtronic Model 9790 programmer, which is microprocessor-based and provides a series of encoded signals to IMD **10**, typically through a programming head which transmits or telemeters radio-frequency (RF) encoded signals to IMD **10**. Such a telemetry system is described in U.S. Patent No. 5,312,453 to Wyborny *et al.*, hereby incorporated by reference herein in its entirety. The programming methodology disclosed in U.S. Patent No. 5,312,453 to Wyborny *et al.* is identified herein for illustrative purposes only. Any of a number of suitable programming and telemetry methodologies known in the art may be employed so long as the desired information is transmitted to and from the pacemaker.

As shown in **FIG. 3**, lead **18** is coupled to node **50** in IMD **10** through input capacitor **52**. Activity sensor or accelerometer **11** may be attached to a hybrid circuit located inside hermetically sealed enclosure **14** of IMD **10**. The output signal provided by activity sensor **11** is coupled to input/output circuit **54**. Input/output circuit **54** contains analog circuits for interfacing to heart **8**, activity sensor **11**, antenna **56** and circuits for the application of stimulating pulses to heart **8**. Accordingly, the rate at which heart **8** is stimulated or beats spontaneously without stimulation may be controlled and/or monitored using software-implemented algorithms or pacing rate functions stored in microcomputer circuit **58**.

Microcomputer circuit **58** may comprise on-board circuit **60** and off-board circuit **62**. Circuit **58** may correspond to a microcomputer circuit disclosed in U.S. Patent No. 5,312,453 to Shelton *et al.*, hereby incorporated by reference herein in its entirety. On-board circuit **60** may include microprocessor **64**, system clock circuit **66** and on-board RAM **68** and ROM **70**. Off-board circuit **62** may comprise a RAM/ROM unit. On-board circuit **60** and off-board circuit **62** are each coupled by data communication bus **72** to digital controller/timer circuit **74**. Microcomputer circuit **58** may comprise a custom integrated circuit device augmented by standard RAM/ROM components.

Electrical components shown in **FIG. 3** are powered by an appropriate implantable battery power source **76** in accordance with common practice in the art. For the sake of clarity, the coupling of battery power to the various components of IMD **10** is not shown in the Figures. Antenna **56** is connected to input/output circuit **54** to permit uplink/downlink telemetry through RF transmitter and receiver telemetry unit **78**. By way of example, telemetry unit **78** may correspond to that disclosed in U.S. Patent No. 4,566,063, issued to Thompson *et al.,* hereby incorporated by reference herein in its entirety, or to that disclosed in the above-referenced '453 patent to Wyborny *et al.* It is generally preferred that the particular programming and telemetry scheme selected permit the entry and storage of cardiac rate-response parameters. The specific embodiments of antenna **56,** input/output circuit **54** and telemetry unit **78** presented herein are shown for illustrative purposes only, and are not intended to limit the scope of the present invention.

Continuing to refer to **FIG. 3**, V_{REF} and Bias circuit **82** may generate stable voltage reference and bias currents for analog circuits included in input/output circuit **54**. Analog-to-digital converter (ADC) and multiplexer unit **84** digitizes analog signals and voltages to provide "real-time" telemetry intracardiac signals and battery end-of-life (EOL) replacement functions. Operating commands for controlling the timing of IMD **10** are coupled by data communication bus **72** to digital controller/timer circuit **74**, where digital timers and counters establish the overall escape interval of the IMD **10** as well as various refractory, blanking and other timing windows for controlling the operation of peripheral components disposed within input/output circuit **54**.

Digital controller/timer circuit **74** may be coupled to sensing circuitry, including sense amplifier **88**, peak sense and threshold measurement unit **90** and comparator/threshold detector **92**. Circuit **74** may further be coupled to electrogram (EGM) amplifier **94** for receiving amplified and processed signals sensed by lead **18**. Sense amplifier **88** amplifies sensed electrical cardiac signals and provides an amplified signal to peak sense and threshold measurement circuitry **90**, which in turn provides an indication of peak sensed voltages and measured sense amplifier threshold voltages on multiple conductor signal path **67** to digital controller/timer circuit **74**. An amplified sense amplifier signal is then provided to comparator/threshold detector **92**. By way of example, sense amplifier **88** may correspond to that disclosed in U.S. Patent No. 4,379,459 to Stein, hereby incorporated by reference herein in its entirety.

The electrogram signal provided by EGM amplifier **94** is employed when IMD **10** is being interrogated by an external programmer to transmit a representation of a cardiac analog electrogram. See, for example, U.S. Patent No. 4,556,063 to Thompson *et al.*, hereby incorporated by reference herein in its entirety. Output pulse generator **96** provides pacing stimuli to patient's heart **8** through coupling capacitor **98** in response to a pacing trigger signal provided by digital controller/timer circuit **74** each time the escape interval times out, an externally transmitted pacing command is received or in response to other stored commands as is well known in the pacing art. By way of example, output amplifier **96** may correspond generally to an output amplifier disclosed in U.S. Patent No. 4,476,868 to Thompson, hereby incorporated by reference herein in its entirety.

The specific embodiments of input amplifier **88**, output amplifier **96** and EGM amplifier **94** identified herein are presented for illustrative purposes only, and are not intended to be limiting in respect of the scope of the present invention. The specific embodiments of such circuits may not be critical to practicing some embodiments of the present invention so long as they provide means for generating a stimulating pulse and are capable of providing signals indicative of natural or stimulated contractions of heart **8**.

In some preferred embodiments of the present invention, IMD **10** may operate in various non-rate-responsive modes, including, but not limited to, DDD, DDI, VVI, VOO and VVT modes. In other preferred embodiments of the present invention, IMD **10** may operate in various rate-responsive, including, but not limited to, DDDR, DDIR, VVIR, VOOR and VVTR modes. Some embodiments of the present invention are capable of operating in both non-rate-responsive and rate responsive modes. Moreover, in various embodiments of the present invention IMD **10** may be programmably configured to operate so that it varies the rate at which it delivers stimulating pulses to heart **8** only in response to one or more selected sensor outputs being generated. Numerous pacemaker features and

functions not explicitly mentioned herein may be incorporated into IMD **10** while remaining within the scope of the present invention.

The present invention is not limited in scope to single-sensor or dual-sensor pacemakers, and is not limited to IMDs comprising activity or pressure sensors only. Nor is the present invention limited in scope to single-chamber pacemakers, single-chamber leads for pacemakers or single-sensor or dual-sensor leads for pacemakers. Thus, various embodiments of the present invention may be practiced in conjunction with more than two leads or with multiple-chamber pacemakers, for example. At least some embodiments of the present invention may be applied equally well in the contexts of single-, dual-, triple- or quadruple-chamber pacemakers or other types of IMDs. See, for example, U.S. Patent No. 5,800,465 to Thompson *et al.*, hereby incorporated by reference herein in its entirety, as are all U.S. Patents referenced therein.

IMD **10** may also be a pacemaker-cardioverter- defibrillator ("PCD") corresponding to any of numerous commercially available implantable PCDs. Various embodiments of the present invention may be practiced in conjunction with PCDs such as those disclosed in U.S. Patent No. 5,545,186 to Olson *et al.*, U.S. Patent No. 5,354,316 to Keimel, U.S. Patent No. 5,314,430 to Bardy, U.S. Patent No. 5,131,388 to Pless and U.S. Patent No. 4,821,723 to Baker *et al.*, all of which are hereby incorporated by reference herein, each in its respective entirety.

FIGS. 4 and **5** illustrate one embodiment of IMD **10** and a corresponding lead set of the present invention, where IMD **10** is a PCD. In **FIG. 4**, the ventricular lead takes the form of leads disclosed in U.S. Patent Nos. 5,099,838 and 5,314,430 to Bardy, and includes an elongated insulative lead body **1** carrying three concentric coiled conductors separated from one another by tubular insulative sheaths. Located adjacent the distal end of lead **1** are ring electrode **2**, extendable helix electrode **3** mounted retractably within insulative electrode head **4** and elongated coil electrode **5**. Each of the electrodes is coupled to one of the coiled conductors within lead body **1**. Electrodes **2** and **3** may be employed for cardiac pacing and for sensing ventricular depolarizations. At the proximal end of the lead is bifurcated connector **6**, which carries three electrical connectors, each coupled to one of the coiled conductors. Defibrillation electrode **5** may be fabricated from platinum, platinum alloy or other materials known to be usable in implantable defibrillation electrodes and may be about **5** cm in length.

The atrial/SVC lead shown in **FIG. 4** includes elongated insulative lead body **7** carrying three concentric coiled conductors separated from one another by tubular insulative sheaths corresponding to the structure of the ventricular lead. Located adjacent the J-shaped distal end of the lead are ring electrode **9** and extendable helix electrode **13** mounted retractably within an insulative electrode head **15**. Each of the electrodes is coupled to one of the coiled conductors within lead body **7**. Electrodes **13** and **9** may be employed for atrial pacing and for sensing atrial depolarizations. Elongated coil electrode **19** is provided proximal to electrode **9** and coupled to the third conductor within lead body **7**. In one embodiment of the invention, electrode **19** is **10** cm in length or greater and is configured to extend from the SVC toward the tricuspid valve. In one embodiment of the present invention, approximately **5** cm of the right atrium/SVC electrode is located in the right atrium with the remaining **5** cm

located in the SVC. At the proximal end of the lead is bifurcated connector **17**, which carries three electrical connectors, each coupled to one of the coiled conductors.

The coronary sinus lead shown in **FIG. 4** assumes the form of a coronary sinus lead disclosed in the above cited '838 patent issued to Bardy, and includes elongated insulative lead body **41** carrying one coiled conductor coupled to an elongated coiled defibrillation electrode **21**. Electrode **21**, illustrated in broken outline in **FIG. 4**, is located within the coronary sinus and the great vein of the heart. At the proximal end of the lead is connector plug **23** carrying an electrical connector coupled to the coiled conductor. The coronary sinus/great vein electrode **41** may be about **5** cm in length.

Implantable PCD **10** is shown in **FIG. 4** in combination with leads **1**, **7** and **41**, and lead connector assemblies **23**, **17** and **6** inserted into connector block **12**. Optionally, insulation of the outward facing portion of housing **14** of PCD **10** may be provided using a plastic coating such as parylene or silicone rubber, as is employed in some unipolar cardiac pacemakers. The outward facing portion, however, may be left uninsulated or some other division between insulated and uninsulated portions may be employed. The uninsulated portion of housing **14** serves as a subcutaneous defibrillation electrode to defibrillate either the atria or ventricles. Lead configurations other than those shown in **FIG. 4** may be practiced in conjunction with the present invention, such as those shown in U.S. Patent No. 5,690,686 to Min *et al.*, hereby incorporated by reference herein in its entirety.

FIG. 5 is a functional schematic diagram of one embodiment of implantable PCD **10** of the present invention. This diagram should be taken as exemplary of the type of device in which various embodiments of the present invention may be embodied, and not as limiting, as it is believed that the invention may be practiced in a wide variety of device implementations, including cardioverter and defibrillators which do not provide anti-tachycardia pacing therapies.

IMD **10** is provided with an electrode system. If the electrode configuration of **FIG. 4** is employed, the correspondence to the illustrated electrodes is as follows. Electrode **25** in **FIG. 5** includes the uninsulated portion of the housing of PCD **10**. Electrodes **25, 15, 21** and **5** are coupled to high voltage output circuit **27**, which includes high voltage switches controlled by CV/defib control logic **29** via control bus **31**. Switches disposed within circuit **27** determine which electrodes are employed and which electrodes are coupled to the positive and negative terminals of the capacitor bank (which includes capacitors **33** and **35**) during delivery of defibrillation pulses.

Electrodes **2** and **3** are located on or in the ventricle and are coupled to the R-wave amplifier **37**, which may take the form of an automatic gain controlled amplifier providing an adjustable sensing threshold as a function of the measured R-wave amplitude. A signal is generated on R-out line **39** whenever the signal sensed between electrodes **2** and **3** exceeds the present sensing threshold.

Electrodes **9** and **13** are located on or in the atrium and are coupled to the P-wave amplifier **43**, which may also take the form of an automatic gain controlled amplifier providing an adjustable sensing threshold as a function of the measured P-wave amplitude. A signal is generated on P-out line **45** whenever the signal sensed between electrodes **9** and **13** exceeds the present sensing threshold. The general operation of R-wave and P-wave amplifiers **37** and **43** may correspond to that disclosed in U.S. Patent No. 5,117,824, by Keimel *et al.*, issued Jun. 2, 1992, for "An Apparatus for Monitoring Electrical Physiologic Signals", hereby incorporated by reference herein in its entirety.

Switch matrix **47** is used to select which of the available electrodes are coupled to wide band (0.5-200 Hz) amplifier **49** for use in digital signal analysis. Selection of electrodes is controlled by the microprocessor **51** via data/address bus **53**, which selections may be varied as desired. Signals from the electrodes selected for coupling to bandpass amplifier **49** are provided to multiplexer **55**, and thereafter converted to multi-bit digital signals by A/D converter **57**, for storage in random access memory **59** under control of direct memory access circuit **61**. Microprocessor **51** may employ digital signal analysis techniques to characterize the digitized signals stored in random access memory **59** to recognize and classify the patient's heart rhythm employing any of the numerous signal-processing methodologies known to the art.

The remainder of the circuitry is dedicated to the provision of cardiac pacing, cardioversion and defibrillation therapies, and, for purposes of the present invention, may correspond to circuitry known to those skilled in the art. The following exemplary apparatus is disclosed for accomplishing pacing, cardioversion and defibrillation functions. Pacer timing/control circuitry **63** may include programmable digital counters which control the basic time intervals associated with DDD, VVI, DVI, VDD, AAI, DDI and other modes of single and dual chamber pacing well known to the art. Circuitry **63** also may control escape

intervals associated with anti-tachyarrhythmia pacing in both the atrium and the ventricle, employing any anti-tachyarrhythmia pacing therapies known to the art.

Intervals defined by pacing circuitry **63** include atrial and ventricular pacing escape intervals, the refractory periods during which sensed P-waves and R-waves are ineffective to restart timing of the escape intervals and the pulse widths of the pacing pulses. The durations of these intervals are determined by microprocessor **51**, in response to stored data in memory **59** and are communicated to pacing circuitry **63** via address/data bus **53**. Pacer circuitry **63** also determines the amplitude of the cardiac pacing pulses under control of microprocessor **51**.

During pacing, escape interval counters within pacer timing/control circuitry **63** are reset upon sensing of R-waves and P-waves as indicated by signals on lines **39** and **45**, and in accordance with the selected mode of pacing on time-out trigger generation of pacing pulses by pacer output circuitry **65** and **67**, which are coupled to electrodes **9**, **13**, **2** and **3**. Escape interval counters are also reset on generation of pacing pulses and thereby control the basic timing of cardiac pacing functions, including anti-tachyarrhythmia pacing. The durations of the intervals defined by escape interval timers are determined by microprocessor **51** via data/address bus **53**. The value of the count present in the escape interval counters when reset by sensed R-waves and P-waves may be used to measure the durations of R-R intervals, P-P intervals, P-R intervals and R-P intervals, which measurements are stored in memory **59** and used to detect the presence of tachyarrhythmias.

Microprocessor **51** may operate as an interrupt driven device, and may be responsive to interrupts from pacer timing/control circuitry **63** corresponding to the occurrence of sensed P-waves and R-waves and corresponding to the generation of cardiac pacing pulses. Those interrupts are provided via data/address bus **53**. Any necessary mathematical calculations to be performed by microprocessor **51** and any updating of the values or intervals controlled by pacer timing/control circuitry **63** take place following such interrupts.

Detection of atrial or ventricular tachyarrhythmias, as employed in the present invention, may correspond to any of the various tachyarrhythmia detection algorithms presently known in the art. For example, the presence of an atrial or ventricular tachyarrhythmia may be confirmed by detecting a sustained series of short R-R or P-P intervals of an average rate indicative of tachyarrhythmia or an unbroken series of short R-R or P-P intervals. The suddenness of onset of the detected high rates, the stability of the high rates, and a number of other factors known in the art may also be measured at this time. Appropriate ventricular tachyarrhythmia detection methodologies measuring such factors are described in U.S. Patent No. 4,726,380 issued to Vollmann, U.S. Patent No. 4,880,005, issued to Pless *et al.* and U.S. Patent No. 4,830,006, issued to Haluska *et al.*, all hereby incorporated by reference herein, each in its respective entirety. An additional set of tachycardia recognition methodologies is disclosed in the article "Onset and Stability for Ventricular Tachyarrhythmia Detection in an Implantable Pacer-Cardioverter-Defibrillator" by Olson *et al.*, published in Computers in Cardiology, Oct. 7-10, 1986, IEEE Computer Society Press, pages 167-170, also incorporated by reference herein in its entirety. Atrial fibrillation detection methodologies are disclosed in Published PCT Application Ser. No. US92/02829, Publication No. WO92/18198, by Adams *et al.*, and in the article "Automatic Tachycardia Recognition", by Arzbaecher et al., published in PACE,

May-June, 1984, pp. 541-547, both of which are hereby incorporated by reference herein, each in its respective entirety.

In the event an atrial or ventricular tachyarrhythmia is detected and an anti-tachyarrhythmia pacing regimen is desired, appropriate timing intervals for controlling generation of anti-tachyarrhythmia pacing therapies are loaded from microprocessor **51** into the pacer timing and control circuitry **63**, to control the operation of the escape interval counters therein and to define refractory periods during which detection of R-waves and P-waves is ineffective to restart the escape interval counters.

Alternatively, circuitry for controlling the timing and generation of anti-tachycardia pacing pulses as described in U.S. Patent No. 4,577,633, issued to Berkovits *et al*. on Mar. 25, 1986, U.S. Patent No. 4,880,005, issued to Pless *et al.* on Nov. 14, 1989, U.S. Patent No. 4,726,380, issued to Vollmann et al. on Feb. 23, 1988 and U.S. Patent No. 4,587,970, issued to Holley *et al.* on May 13, 1986, all of which are hereby incorporated herein by reference, each in its respective entirety, may also be employed.

In the event that generation of a cardioversion or defibrillation pulse is required, microprocessor **51** may employ an escape interval counter to control timing of such cardioversion and defibrillation pulses, as well as associated refractory periods. In response to the detection of atrial or ventricular fibrillation or tachyarrhythmia requiring a cardioversion pulse, microprocessor **51** activates cardioversion/defibrillation control circuitry **29**, which initiates charging of the high voltage capacitors **33** and **35** via charging circuit **69**, under the control of high voltage charging control line **71**. The voltage on the high voltage capacitors is monitored via VCAP line **73**, which is passed through multiplexer **55** and in response to reaching a predetermined value set by microprocessor **51**, results in generation of a logic signal on Cap Full (CF) line **77** to terminate charging.

Thereafter, timing of the delivery of the defibrillation or cardioversion pulse is controlled by pacer timing/control circuitry **63**. Following delivery of the fibrillation or tachycardia therapy, microprocessor **51** returns the device to a cardiac pacing mode and awaits the next successive interrupt due to pacing or the occurrence of a sensed atrial or ventricular depolarization.

Several embodiments of appropriate systems for the delivery and synchronization of ventricular cardioversion and defibrillation pulses and for controlling the timing functions related to them are disclosed in U.S. Patent No. 5,188,105 to Keimel, U.S. Patent No. 5,269,298 to Adams et al. and U.S. Patent No. 4,316,472 to Mirowski *et al.*, all of which are hereby incorporated by reference herein, each in its respective entirety. Any known cardioversion or defibrillation pulse control circuitry is believed to be usable in conjunction with various embodiments of the present invention, however. For example, circuitry controlling the timing and generation of cardioversion and defibrillation pulses such as that disclosed in U.S. Patent No. 4,384,585 to Zipes, U.S. Patent No. 4,949,719 to Pless *et al.*, or U.S. Patent No. 4,375,817 to Engle *et al.*, all of which are hereby incorporated by reference herein, each in its respective entirety, may also be employed.

Continuing to refer to **FIG. 5**, delivery of cardioversion or defibrillation pulses may be accomplished by output circuit **27** under the control of control circuitry **29** via control bus **31**. Output circuit **27** determines whether a monophasic or biphasic pulse is delivered, the polarity of the electrodes and which electrodes are involved in delivery of the pulse. Output circuit **27** also includes high voltage switches, which control whether electrodes are coupled together during delivery of the pulse. Alternatively, electrodes intended to be coupled together during the pulse may simply be permanently coupled to one another, either exterior to or within the interior of the device housing, and polarity may similarly be pre-set, as in current implantable defibrillators. An example of

output circuitry for delivery of biphasic pulse regimens to multiple electrode systems may be found in U.S. Patent No. 4,953,551, issued to Mehra, and in U.S. Patent No. 4,727,877,both of which are hereby incorporated by reference herein in its entirety.

An example of circuitry that may be used to control delivery of monophasic pulses is disclosed in U.S. Patent No. 5,163,427 to Keimel, also hereby incorporated by reference herein in its entirety. Output control circuitry similar to that disclosed in U.S. Patent No. 4,953,551 to Mehra et al. or U.S. Patent No. 4,800,883 to Winstrom, both incorporated by reference, each in its respective entirety, may also be used in conjunction with various embodiments of the present invention to deliver biphasic pulses.

Alternatively, IMD **10** may be an implantable nerve stimulator or muscle stimulator such as that disclosed in U.S. Patent No. 5,199,428 to Obel *et al.*, U.S. Patent No. 5,207,218 to Carpentier *et al.* or U.S. Patent No. 5,330,507 to Schwartz, or an implantable monitoring device such as that disclosed in U.S. Patent No. 5,331,966 issued to Bennet *et al.*, all of which are hereby incorporated by reference herein, each in its respective entirety. The present invention is believed to find wide application to any form of implantable electrical device for use in conjunction with electrical leads.

FIG. 6 is a simplified schematic view of one embodiment of an implantable medical device ("IMD") **10** for comparison with the embodiments of the present invention.

IMD **10** is connected to heart **8** through a series of leads **16** and **18**. In the embodiment of **FIG. 6,** lead **18** couples a ventricular circuit to the right ventricle; however, lead **18** could also be coupled to the left ventricle. Ventricular circuit may provide for the sensing and stimulation of the ventricle in any suitable manner as is known in the art and described above. Lead **18** may be, for example a unipolar endocardial lead as described above or any suitable lead

well known in the art. Lead **18** features two electrodes **28** and **29** at its distal end. Electrodes **28, 29** may be used for stimulation of one of the ventricles, in the case of **FIG. 6**, the right ventricle. In the embodiment of **FIG. 6,** lead **16** couples an atrial circuit to the right atrium; however, lead **16** could also be coupled to the left atrium. Atrial circuit may provide for the sensing and stimulation of the atria in any suitable manner as is known in the art and described above. Lead **16** may be, for example, a unipolar endocardial lead as described above or any suitable lead well known in the art. Lead **16** features two electrodes **20** and **621** at its distal end. Electrodes **20, 21** may be used for stimulation of one of the atria, in the case of **FIG. 6**, the right atria.

Input/output circuit **54** of IMD **10** may be configured to sense cardiac activity in each of the respective chambers and also to provide electrical stimulation in response thereto.

FIG. 7 is a simplified schematic view of one embodiment of an implantable medical device ("IMD") **10** in accordance with the present invention.

Pacing leads **16** and **18** extend from connector header module **12** to the left and right ventricles, respectively, of heart **8**. In one embodiment of the invention, leads **16, 18** are selectively insertable into connector header module **12** depending on the desired configuration (i.e., the leads are inserted in one configuration to provide the embodiment of **FIG. 7** and in other configurations to provide other embodiments.) For example, the leads may be coupled prior to implantation. Lead **18** couples an input/output circuit **54** of IMD **10** to the right ventricle. Input/output circuit **54** may provide for the sensing and stimulation of the ventricles in any suitable manner as is known in the art and described above. Lead **18** may be, for example a unipolar endocardial lead as described above or any suitable lead well known in the art. Lead **18** may comprise two ventricular electrodes **28** and **29** at its distal end. In the embodiment of **FIG. 7,** electrode **29** serves as a cathode and is coupled to the right ventricle. Meanwhile, electrode

28 serves as an anode to electrode **29** and is not connected with the circuit or is not in use for this configuration.

Lead **16** couples input/output circuit **54** of IMD **10** to the left ventricle. Input/output circuit **54** may provide for the sensing and stimulation of the ventricles in any suitable manner as is known in the art and described above. Lead **16** may be, for example, a unipolar endocardial lead as described above or any suitable lead well known in the art. Lead **16** may comprise two atrial electrodes **20** and **21** at its distal end. In the embodiment of **FIG. 7,** electrode **21** serves as a cathode and is coupled to the left ventricle. Meanwhile, electrode **20** serves as an anode to electrode **21** and is not connected with the circuit or is not in use for this configuration.

Input/output circuit **54** of IMD **10** may be configured to sense cardiac activity in each of the respective chambers and also to provide electrical stimulation in response thereto. For example, input/output circuit **54** may be configured to disable connectivity of electrode **28** and/connectivity of electrode **20** to accomplish the configuration shown in **FIG. 7** (i.e., where electrodes **28, 20** are "not connected"). In some embodiments of the invention, the switch matrix may accomplish a switch from a unipolar lead configuration to a bipolar lead configuration as described above. Such a switch may be accomplished using switching transistors and circuitry disposed within IMD **10.**

FIG. 8 is a simplified schematic view of another configuration for the embodiment of IMD **10** shown in **FIG. 7**. With the configuration shown in **FIG. 8**, unipolar pacing stimulation may be delivered to the right ventricle. Additionally, sensing pulses may be delivered to either of the ventricles in a unipolar or bipolar fashion.

For example, in the embodiment shown in **FIG. 8,** the right ventricle will receive a unipolar pacing pulse from cathode **29** while the left ventricle into which cathode **21** has been placed will not receive a pacing pulse. That is, the pathway

of current from cathode **21** may be, for example, through the heart muscle wall through the body to connector header module **12.** In the embodiment of **FIG. 8,** electrode **28** is not connected with the circuit or is not in use for this configuration. Meanwhile, electrode **20** is also not connected with the circuit or is not in use for this configuration.

Input/output circuit **54** of IMD **10** may be configured to sense cardiac activity in each of the respective chambers and also to provide electrical stimulation in response thereto. For example, input/output circuit **54** may be configured to route connectivity of electrode **21** to connector header module **12** and to disable connectivity of electrode **28** and/connectivity of electrode **20** to accomplish the configuration shown in **FIG. 8** (i.e., where electrodes **28, 20** are "not connected"). Such a switch may be accomplished using switching transistors and circuitry disposed within IMD **10.**

FIG. 9 is a simplified schematic view of another configuration for the embodiment of IMD **10** shown in **FIG. 7**. With the configuration shown in **FIG. 9,** unipolar pacing stimulation may be delivered to the left ventricle. Additionally, sensing pulses may be delivered to either of the ventricles in a unipolar or bipolar fashion.

For example, in the embodiment shown in **FIG. 9,** the left ventricle will receive a unipolar pacing pulse from cathode **21** while the right ventricle into which cathode **29** has been placed will not receive a pacing pulse. That is, the pathway of current from cathode **29** may be, for example, through the heart muscle wall through the body to connector header module **12.** In the embodiment of **FIG. 9,** electrode **28** is not connected with the circuit or is not in use for this configuration. Meanwhile, electrode **20** is also not connected with the circuit or is not in use for this configuration.

Input/output circuit **54** of IMD **10** may be configured to sense cardiac activity in each of the respective chambers and also to provide electrical

stimulation in response thereto. For example, input/output circuit **54** may be configured to route connectivity of electrode **21** to connector header module **12** and to disable connectivity of electrode **28** and/connectivity of electrode **20** to accomplish the configuration shown in **FIG. 9** (i.e., where electrodes **28, 20** are "not connected"). Such a switch may be accomplished using switching transistors and circuitry disposed within IMD **10.**

FIG. 10 is a simplified schematic view of another configuration for the embodiment of IMD **10** shown in **FIG. 7**. With the configuration shown in **FIG. 10**, bipolar pacing stimulation may be achieved in both ventricular chambers, with delivery from the right to the left ventricle. Additionally, sensing pulses may be delivered to either of the ventricles in a unipolar or bipolar fashion.

Pacing leads **16** and **18** extend from connector header module **12** to the left and right ventricles, respectively, of heart **8**. In one embodiment of the invention, leads **16, 18** are selectively insertable into connector header module **12** depending on the desired configuration (i.e., the leads are inserted in one configuration to provide the embodiment of **FIG. 10** and in other configurations to provide other embodiments.) For example, the leads may be coupled prior to implantation. Lead **18** couples an input/output circuit **54** of IMD **10** to the right ventricle. Input/output circuit **54** may provide for the sensing and stimulation of the ventricles in any suitable manner as is known in the art and described above. Lead **18** may be, for example a unipolar endocardial lead as described above or any suitable lead well known in the art. Lead **18** may comprise two ventricular electrodes **28** and **29** at its distal end. In the embodiment of **FIG. 10,** electrode **21** serves as a cathode and is coupled to the left ventricle. Meanwhile, electrode **29** serves as an anode to electrode **21** and is coupled to the right ventricle while electrode **20** serves to complete the circuit to electrode **29.** Finally, electrode **28** is not connected with the circuit or is not in use for this configuration.

Input/output circuit **54** of IMD **10** may be configured to sense cardiac activity in each of the respective chambers and also to provide electrical stimulation in response thereto. For example, input/output circuit **54** may be configured to route connectivity of electrode **20** to electrode **29** and to disable connectivity of electrode **28** to accomplish the configuration shown in **FIG. 9** (i.e., where electrode **28** is "not connected").

FIG. 11 is a simplified schematic view of another configuration for the embodiment of IMD **10** shown in **FIG. 7**. With the configuration shown in **FIG. 11**, bipolar pacing stimulation may be achieved in both ventricular chambers, with delivery from the left to the right ventricle. Additionally, sensing pulses may be delivered to either of the ventricles in a unipolar or bipolar fashion.

In the embodiment of **FIG. 11**, electrode **29** serves as a cathode and is coupled to the right ventricle. Meanwhile, electrode **21** serves as an anode to electrode **29** and is coupled to the left ventricle while electrode **28** serves to complete the circuit to electrode **21**. Finally, electrode **20** is not connected with the circuit or is not in use for this configuration.

Input/output circuit **54** of IMD **10** may be configured to sense cardiac activity in each of the respective chambers and also to provide electrical stimulation in response thereto. For example, input/output circuit **54** may be configured to route connectivity of electrode **28** to electrode **21** and to disable connectivity of electrode **20** to accomplish the configuration shown in **FIG. 11** (i.e., where electrode **20** is "not connected").

As can be seen from the above, the configurations of the electrodes **20** and **28** which are not directly connected to the heart, and of electrodes **21** and **28** disposed in opposing ventricles of the heart, are switchable. Moreover, the polarity of various electrodes is selectable or switchable. In the embodiments described in **FIGS. 6-10**, the leads employed are unipolar. In alternate embodiments of the

invention, bipolar leads may be employed as well. Additionally, electrodes **20, 21** and electrodes **28, 29** may be similarly disposed in opposing atria of the heart.

FIG. 12 shows one embodiment of a method for stimulating a heart in accordance with the teachings of the present invention. As discussed above, the method of the present invention may be performed under the control of any appropriate computer algorithm stored in a memory or a portion of a memory of microcomputer **58** in IMD **10**. Such a computer algorithm may be any program capable of being stored in an electronic medium such as, by way of example only, RAM **68** or ROM **70** of IMD **10**, where the contents of RAM **68** and ROM **70** may be accessed and consequently executed by microprocessor **64**/microcomputer **58**.

As shown at block **710**, it may be determined which chamber of a left and a right chamber of heart **8** requires the higher threshold pacing pulse. This determination may be made for example, by comparing the required threshold pacing pulse for the right atrium to the required threshold pacing pulse for the left atrium and vice versa. Alternatively, the required threshold pacing pulse for the right ventricle may be compared to the required threshold pacing pulse for the left ventricle and vice versa.

The cathode may be assigned to the chamber that requires the higher threshold. In some embodiments of the invention, threshold measurements are taken and the chamber requiring higher threshold pacing pulses is automatically assigned the cathode. This assignment may be made automatically, for example by a computer algorithm and/or program capable of being stored in an electronic medium such as, by way of example only, RAM **68** or ROM **70** of IMD **10**, where the contents of RAM **68** and ROM **70** may be accessed and consequently executed by microprocessor **64**/microcomputer **58**. Alternatively, a physician may manually assign the cathode.

Once the cathode has been assigned, the method of the present invention may proceed according to two paths such as, for example, those shown in **FIG.**

12. In the first path, beginning at block **720**, the electrode in the left chamber is assigned as the cathode. At block **730**, the electrode in the right chamber is then assigned as the anode. At block **740**, it is determined whether the stimulation pulse will be a pacing or a sensing pulse. At block **750**, it is determined whether the cathode will act as a unipolar electrode or as a bipolar electrode. If, as seen at block **752**, the cathode will act as a unipolar electrode, a single pulse will be administered from the cathode to tissue within the left chamber. If, as seen at block **754**, the cathode will act as a bipolar electrode, a single pulse will be administered from the cathode to the anode, thus simultaneously administering stimulation to tissue in both the left and the right chambers.

In the second path, beginning at block **725**, the electrode in the right chamber is assigned as the cathode. At block **735**, the electrode in the left chamber is then assigned as the anode. At block **745**, it is determined whether the stimulation pulse will be a pacing or a sensing pulse. At block **755**, it is determined whether the cathode will act as a unipolar electrode or as a bipolar electrode. If, as seen at block **757**, the cathode will act as a unipolar electrode, a single pulse will be administered from the cathode to tissue within the right chamber. If, as seen at block **759**, the cathode will act as a bipolar electrode, a single pulse will be administered from the cathode to the anode, thus simultaneously administering stimulation to tissue in both the left and the right chambers.

In some embodiments of the invention, the pacing mode may determine in which direction the stimulus is administered, i.e., whether the stimulation is administered from the right atrium to the left atrium or from the left atrium to the right atrium, the right ventricle to the left ventricle or from the left ventricle to the right ventricle. The mode may further determine the type of sensing configuration of the electrodes. **Table 2** lists some examples of modes, the resulting direction of the stimulation pulse, and the resulting sensing configuration of the electrodes.

Table 2

MODE	SENSING	PACING	PULSE DELIVERED
V_2 V_2I (FIG. 7)	Bipolar	Unipolar	bipolar sensing stimulation delivered from left electrode to left ventricle AND right electrode to right ventricle unipolar pacing stimulation delivered from left electrode to left ventricle and right electrode to right ventricle
V_1 V_1I (FIG. 8)	Unipolar	Unipolar	unipolar sensing stimulation delivered from right electrode to right ventricle (unused electrode is routed to pacemaker can) unipolar pacing stimulation delivered from right electrode to right ventricle (unused electrode is routed to pacemaker can)
V_1 V_1I (FIG. 9)	Unipolar	Unipolar	unipolar sensing stimulation delivered from left electrode to left ventricle (unused electrode is routed to pacemaker can) unipolar pacing stimulation delivered from left electrode to left ventricle (unused electrode is routed to pacemaker can)
V_{12} V_{12}I (FIG. 10)	bipolar	bipolar	bipolar sensing stimulation delivered from right electrode to left ventricle bipolar sensing stimulation delivered from right electrode to left ventricle
V_{21} V_{21}I (FIG. 11)	bipolar	bipolar	bipolar sensing stimulation delivered from left electrode to right ventricle bipolar sensing stimulation delivered from left electrode to right ventricle

In some embodiments of the invention, once the proper polarities and electrode assignments of the leads have been established, bipolar stimulation may proceed in a first direction, i.e., from a first opposing chamber to a second opposing chamber. For example, stimulation may proceed from the left ventricle to the right ventricle. In such cases, simultaneous pacing stimulation occurs.

Alternatively, some embodiments may provide unipolar stimulation. In some embodiments, a unipolar stimulation pulse may be delivered in each chamber and followed very quickly by one or more successive stimulation pulses. The successive stimulation pulse may be administered for example any suitable time after the first pulse, for example from 0 to 100 msecs, 10 to 90 msecs, 20 to 80 msecs or 30 to 70 msecs after the first stimulation pulse is administered. Such staggered stimulation permits the induced contractions of the opposing chamber to be optimized from a hemodynamic perspective. That is, pumping efficiency and output of the heart may be increased by use of slight inter-chamber timing delays between two opposing chambers of heart **8**, such as between the two ventricles or between the two atria.

FIG. 13 shows another embodiment of a method for stimulating a heart in accordance with the teachings of the present invention. As discussed above, the method of the present invention may be performed under the control of any appropriate computer algorithm stored in a memory or a portion of a memory of microcomputer **58** in IMD **10**. Such a computer algorithm may be any program capable of being stored in an electronic medium such as, by way of example only, RAM **68** or ROM **70** of IMD **10**, where the contents of RAM **68** and ROM **70** may be accessed and consequently executed by microprocessor **64**/microcomputer **58**.

As seen at block **805** and described above, the opposing chambers of the heart in which the electrodes are to be disposed is selected. At least one first electrode and at least one second electrode may be disposed in the selected

opposing chambers of the heart. For example, the right and left atria may be selected or the right and left ventricles.

As seen at block **810** and described above, a type of pulse may be selected. For example a pacing pulse or a sensing pulse may be selected.

At block **820,** a desired electrode configuration is determined based on the type of stimulation desired. For example, the electrode configuration may result in unipolar pacing of the left or right ventricle, unipolar sensing of the left or right ventricle, bipolar pacing of the left or right ventricle, bipolar sensing of the left or right ventricle, unipolar pacing of the left or right atria, unipolar sensing of the left or right atria, bipolar pacing of the left or right atria, bipolar sensing of the left or right atria.

At block **830** an appropriate cathode is selected based on the desired electrode configuration and at block **840** an appropriate anode is selected based on the desired configuration. For example, in **FIG. 8,** electrode **29** is the cathode and electrode **28** is the anode resulting in an electrode configuration which delivers unipolar pacing of the right ventricle. In **FIG. 9**, electrode **21** is the cathode and electrode **20** is the anode resulting in an electrode configuration that delivers unipolar pacing of the left ventricle.

An additional parameter may be selected at block **850** to determine the direction of the stimulus being delivered. For example, In **FIG. 10,** electrode **21** is the cathode and electrode **29** is the anode resulting in an electrode configuration that delivers bipolar pacing from the right to the left ventricle. In **FIG. 11,** electrode **29** is the cathode and electrode **21** is the anode resulting in an electrode configuration that delivers bipolar pacing from the left to the right ventricle. Other electrode configurations are possible, including corresponding sensing unipolar and bipolar electrode configurations.

At block **860**, the timing of the stimulation may be selected. For example, the electrodes may deliver simultaneous stimulation or staggered stimulation.

At block **870**, the stimulation pulse is delivered. More than one pulse may be delivered based on selections made in the preceding steps.

In the embodiment of the invention seen in **FIGS. 6** through **13**, the parameters determined include: pacing of the right atrium, sensing of the right atrium, pacing of the left atrium, sensing of the left atrium, pacing of the right ventricle, sensing of the right ventricle, pacing of the left ventricle, sensing of the left ventricle, bipolar stimulation or unipolar stimulation, simultaneously delivered pulses or pulses delivered in a staggered fashion. One or any suitable combination of these parameters may be varied in accordance with the present invention. Alternatively, one or more of these parameters may be set at a desired value while one or more other parameters are varied in accordance with the present invention. Moreover, although the parameters are shown as being determined in a given order, these parameters may be determined in any combination and in any order in accordance with the present invention.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, therefore, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the invention or the scope of the appended claims. For example, the present invention is not limited to a method for increasing a pacing parameter of a mammalian heart. The present invention is also not limited to the increase of pacing parameters, *per se,* but may find further application as a measuring means. The present invention further includes within its scope methods of making and using the measurement means described hereinabove.

In the claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents, but also equivalent structures. Thus, although a nail and a screw may not be structural equivalents in that a nail employs a cylindrical surface to secure wooden parts together, whereas a screw employs a helical surface, in the

environment of fastening wooden parts a nail and a screw are equivalent structures.